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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,329	08/21/2003	Amel Amblard	8707-2160	7567

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EXAMINER	
ALEXANDER, JOHN D	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,329	AMBLARD, AMEL	
	Examiner	Art Unit	
	John D. Alexander	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-8,11 and 12* is/are allowed.

6)☒ Claim(s) *9, 10, 13-17, 19-24, 26, and 28-43* is/are rejected.

7)☒ Claim(s) *18, 25, and 27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/21/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed August 21, 2003, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the foreign document EP 0 550 342 has not been considered because no English translation was provided.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 10, 16, 21, 22, and 31-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Regarding **Claims 9, 10, 21, 22, 31, 32, 40, and 41**, the claims recite the limitation "the energy stimulation" in line 2 of each claim. There is insufficient antecedent basis for this limitation in the claims.
- Regarding **Claim 16,** the claim recites the limitation "the atrio-ventricular conduction delay" in line 3. There is insufficient antecedent basis for this limitation in the claim. Furthermore, it is unclear whether Applicant is attempting to claim an additional means for analyzing in

which the means for suspecting loss of capture additionally detects a lengthening of an atrio-ventricular conduction delay.

- Regarding **Claims 33-43**, it is unclear whether Applicant is attempting to claim detecting conditions indicative of suspected loss of atrial capture or detecting conditions indicative of suspected loss of atrial capture *and/or suspected loss of atrial detection.* From Applicant's specification, it seems that the conditions recited in lines 15-19 of Claim 33 are used only for detection of suspected loss of atrial *detection.* Yet, these conditions are claimed as conditions indicative of suspected loss of atrial *capture.* When examining the claims as to the merits, examiner has assumed that Applicant has intended to only claim detecting conditions indicative of suspected loss of atrial capture.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-15, 17, 23, 24, 26, 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Lu et al. (Patent No. 5476486).

- Regarding **Claims 13 and 33**, Lu et al. disclose means for suspecting loss of atrial capture by detection of an absence of ventricular activity post-atrial stimulation (Col. 3, lines 10-15 & 38-47).

- Regarding **Claims 14, 15, 34 and 35**, Lu et al. further disclose that the pulse energy for use by the implanted device is set by, upon detection of absence of ventricular activity post atrial stimulation, increasing the energy to the last level that resulted in successful capture (Col. 4, lines 50-51; Col. 5, lines 22-25). Here, examiner considers that this increase is "relative" to the initial stimulation energy because each of Lu et al's stimulation levels is a result of one or more incremental steps from the initial level.
- Regarding **Claims 17 and 26**, Lu et al. further disclose that, if the atrio-ventricular conduction delay returns to an acceptable length for a particular number of cycles, then capture is assumed and the lowering of the stimulation energy is continued (Col. 5, lines 1-3).
- Regarding **Claim 23**, Lu et al. also disclose means for suspecting loss of atrial capture by detection of a lengthening, beyond a given limit, of an atrio-ventricular conduction delay over a predetermined number of successive cardiac cycles (Col. 4, lines 25-44).
- Regarding **Claim 24,** Lu et al. further disclose that the pulse energy for use by the implanted device is set by, upon detection of a lengthening of the atrio-ventricular conduction delay, increasing the energy to the last level that resulted in successful capture (Col. 4, lines 40-44).

Claims 13-15, 19, 20, 28-30, 33-35, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Markowitz et al. (Patent No. 5601615).

- Regarding **Claims 13 and 33**, Markowitz et al. disclose means for suspecting loss of atrial capture by detection of an absence of ventricular activity post-atrial stimulation (Col. 3, lines 21-27 & 62-66; Col. 22, lines 40-67; Col. 23, lines 1-27).

- Regarding **Claims 14 and 34**, Markowitz et al. further disclose delivering an atrial counter-stimulation in response to a detected absence of ventricular activity post atrial stimulation (Col. 11, lines 62-65; Col. 13, lines 61-67; Col. 24, lines 25-30).
- Regarding **Claims 15 and 35**, Markowitz et al. further disclose that the pulse energy for use by the implanted device is set by, upon detection of absence of ventricular activity post atrial stimulation, increasing the energy to the last level that resulted in successful capture (Col. 24, lines 19-24 & 45-50). Markowitz et al. also disclose that, following the detected loss of capture, a series of "insurance beats" are provided at the previous pulse energy (Col. 4, lines 17-19; Col. 14, lines 15-19; Col. 16,lines 40-46). Here, examiner considers that this increase is "relative" to the initial stimulation energy because each of Markowitz et al.'s stimulation levels is a result of one or more incremental steps from the initial level.
- Regarding **Claims 19, 28, 29, 33, and 35**, Markowitz et al. also disclose means for suspecting loss of atrial capture by detecting an occurrence of atrial detection consecutive to atrial stimulation and means for increasing the atrial stimulation energy relative to the initial setting in response to this detection (Col. 20, lines 7-20&50-63; Col. 21, lines 12-14&28-36).
- Regarding **Claims 20, 30, and 39**, Markowitz et al. further disclose that, as the detection of atrial detection consecutive to atrial stimulation persists, the stimulation energy will eventually reach a maximum level at which the stimulation threshold search is ended (Col. 21, lines 21-22). Here, examiner considers that the stimulation energy is then reset to the initial setting (i.e. since the threshold test is abandoned prior to establishing a successful stimulation energy, it seems that the energy setting would inherently revert to the programmed/operating setting used at commencement of testing. See Col. 16, lines 26-27).

Claims 28, 29, 33, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Bornzin et al. (6389316).

- Regarding **Claims 28 and 33**, Bornzin et al. disclose means for suspecting loss of atrial capture by detection of an occurrence of an atrial detection consecutive to an atrial stimulation over a predetermined number of successive cycles (Col. 5, lines 45-62; Col. 9, lines 65-67; Col. 10, lines 1-5).
- Regarding **Claims 29 and 35**, Bornzin et al. further disclose increasing the atrial stimulation energy over a number of following cycles in response to detection of atrial detection consecutive to atrial stimulation over a predetermined number of successive cycles (Col. 6, lines 3-13).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30-32 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin et al. in view of Markowitz et al.

- Regarding **Claims 30 and 39**, Bornzin et al. do not explicitly disclose that the stimulation energy is restored to the initial setting in response to persistence of the atrial detections

consecutive to atrial stimulations. As related above, Markowitz et al. disclose a similar capture detection system that includes a teaching for the use of a maximum level for the stimulation energy. As the detection of atrial detection consecutive to atrial stimulation persists, the stimulation energy will eventually reach the maximum level, at which time the stimulation threshold search is ended (Col. 20, lines 7-20 & 50-63; Col. 21, lines 12-14, 21-22, & 28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teaching by Markowitz et al. to modify the atrial capture detection system of Bornzin et al. to include a step of restoring the atrial stimulation energy to the initial setting if the suspected loss of capture persists beyond a particular level. The motivation would have been to avoid increasing the stimulation energy to such a large extent that the amplitude becomes unsafe or deleterious to pacemaker or cardiac function.

- Regarding **Claims 31, 32, 40 and 41**, Bornzin et al. further disclose lowering the stimulation energy at periodic intervals in response to a disappearance of the atrial detections consecutive to atrial stimulations (Col. 10, lines 6-14). Here, the lowering is inhibited as long as there is an atrial detection following atrial stimulation, which in the Bornzin et al. capture assessment test, corresponds to an increase in stimulation energy.

Allowable Subject Matter

Claims 1-8, 11, and 12 are allowed. **Claims 9 and 10** would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action. **Claims 16, 21, 22, 36-38, 42, and 43** would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. **Claims 18, 25, and 27** are

objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

- Regarding **Claims 1-12**, it seems that the prior art does not disclose or reasonably suggest an active implantable medical device with means for suspecting a loss of atrial detection and loss of atrial capture that includes means for detecting ***all*** of the following conditions: an absence of ventricular activity post-atrial stimulation, a lengthening, beyond a given limit, of an atrio-ventricular conduction delay over a predetermined number of successive cardiac cycles, an occurrence of an atrial detection consecutive to an atrial stimulation over a predetermined number of successive cardiac cycles, a detection of a ventricular extrasystole, a reduction below a given limit of a delay between an atrial stimulation and a ventricular detection, *and* a passage from an atrial detection to an atrial stimulation with a concomitant reduction, below a given limit, of a delay between an atrial event and a ventricular detection.
- Regarding **Claim 16**, the prior art of record discloses implantable medical devices that include means for suspecting loss of atrial capture by detecting an absence of ventricular activity post-atrial stimulation. The prior art also discloses devices such as these that further include means for increasing the atrial stimulation energy in response to this detected absence of ventricular activity post-atrial stimulation. However, it seems that the prior art does not disclose or reasonably suggest such a device that includes the further functionality of restoring the atrial stimulation energy to the initial setting in response to detection of persistent lengthening of the atrio-ventricular conduction delay.

- Regarding **Claims 18 and 27**, the prior art of record discloses implantable medical devices that include means for suspecting loss of atrial capture by detecting an absence of ventricular activity post-atrial stimulation and by detecting a lengthening of an atrio-ventricular conduction delay. The prior art also discloses devices such as these that further include means for periodically lowering the stimulation energy in response to a disappearance of the detected lengthening of the atrio-ventricular conduction delay. However, it seems that the prior art does not disclose or reasonably suggest such a device that includes the further functionality of inhibiting this periodic lowering of stimulation energy in the event that the stimulation energy has previously been increased over a predetermined number of consecutive intervals.
- Regarding **Claims 21 and 22**, the prior art of record discloses implantable medical devices that include means for suspecting loss of atrial capture by detecting an absence of ventricular activity post-atrial stimulation and by detecting an occurrence of atrial detection consecutive to atrial stimulation. The prior art also discloses devices such as these that further include means for increasing the atrial stimulation energy in response to this detected occurrence of atrial detection consecutive to atrial stimulation and means for restoring the stimulation energy to the initial setting in response to persistence of the detected occurrence of atrial detection consecutive to atrial stimulation. However, it seems that the prior art does not disclose or reasonably suggest such a device that includes the further functionality of lowering the stimulation energy at periodic intervals in response to a disappearance of the atrial detections consecutive to atrial stimulations.

- Regarding **Claims 25 and 36-38**, as related above, the prior art of record discloses implantable medical devices that include means for suspecting loss of atrial capture by detecting a lengthening of an atrio-ventricular conduction delay. The prior art also discloses devices such as these that further include means for increasing the atrial stimulation energy in response to this detected lengthening. However, it seems that the prior art does not disclose or reasonably suggest such a device that includes the further functionality of restoring the atrial stimulation energy to the initial setting if the lengthened atrio-ventricular conduction delay persists.
- Regarding **Claims 42 and 43**, it seems that the prior art does not disclose or reasonably suggest an active implantable medical device with means to detect a condition indicative of suspected loss of atrial capture that further includes means for increasing atrial detection sensitivity.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Alexander whose telephone number is (571) 272-8756. The examiner can normally be reached on Monday-Friday, 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDA

JEFFREY R. JASTRZAB
PRIMARY EXAMINER
3/3/6